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A61F 2/38

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US 4953071 A US 4213209 A US 4209861 A

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(54) Abstract Title
**Total knee replacement prosthesis**

(57) A condylar total knee replacement prosthesis having interacting guide surfaces for control of anterior-posterior displacement. The prosthesis comprises a femoral component 1 having a pair of condylar surfaces 2,3, a tibial component having a tibial platform (4) and a bearing component 8 interposed between the femoral and tibial components. A femoral guide surface 6 is located between the condyles and engages with a tibial guide surface 7 to cause the femoral component to displace posteriorly during flexing movements and displace anteriorly during extending movements. The femoral guide surface has a centre of curvature P which is offset posteriorly and downwardly from the centre of major curvature O of the femoral condyles. In another embodiment, the intercondylar guide is optional.

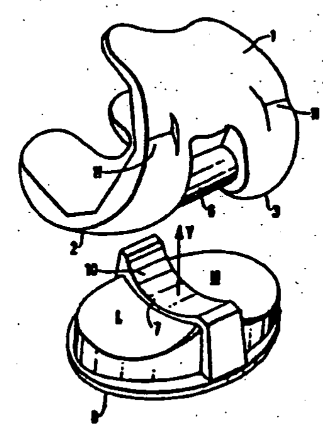

Fig. 1A

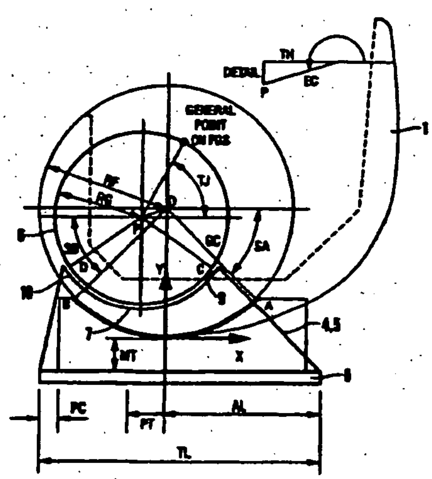


Fig. 1B

GB 2 324 249 A

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

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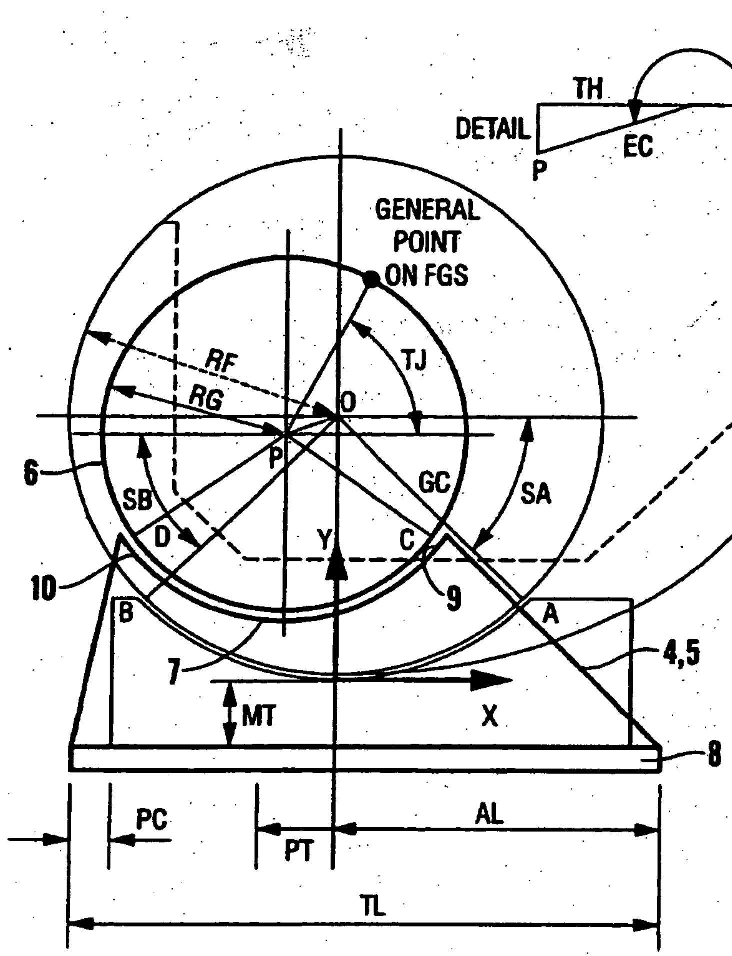

TH
DETAIL
P
EC
1
GENERAL
POINT
ON FGS
RF
TJ
RG
O
P
6
SB
GC
SA
D
Y
C
10
9
B
A
4,5
7
MT
X
8
PC
PT
AL
TL

Fig. 1B

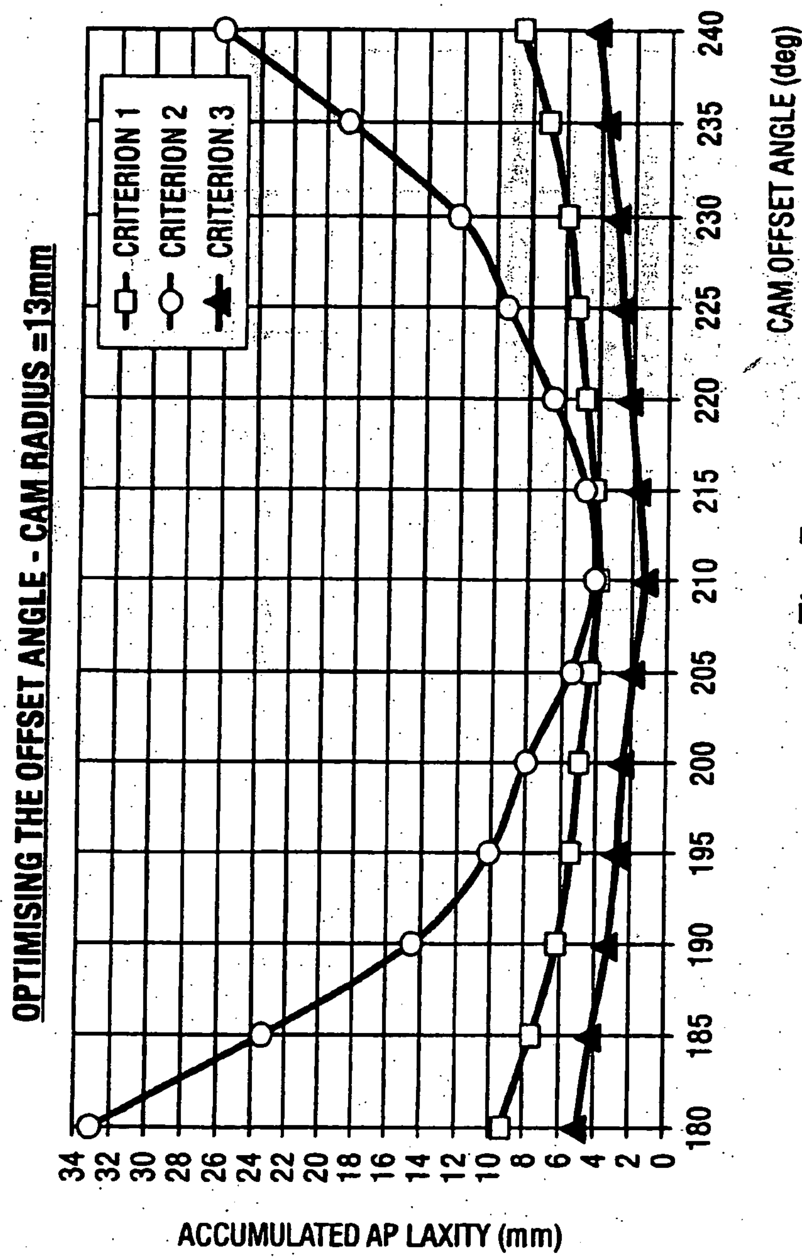
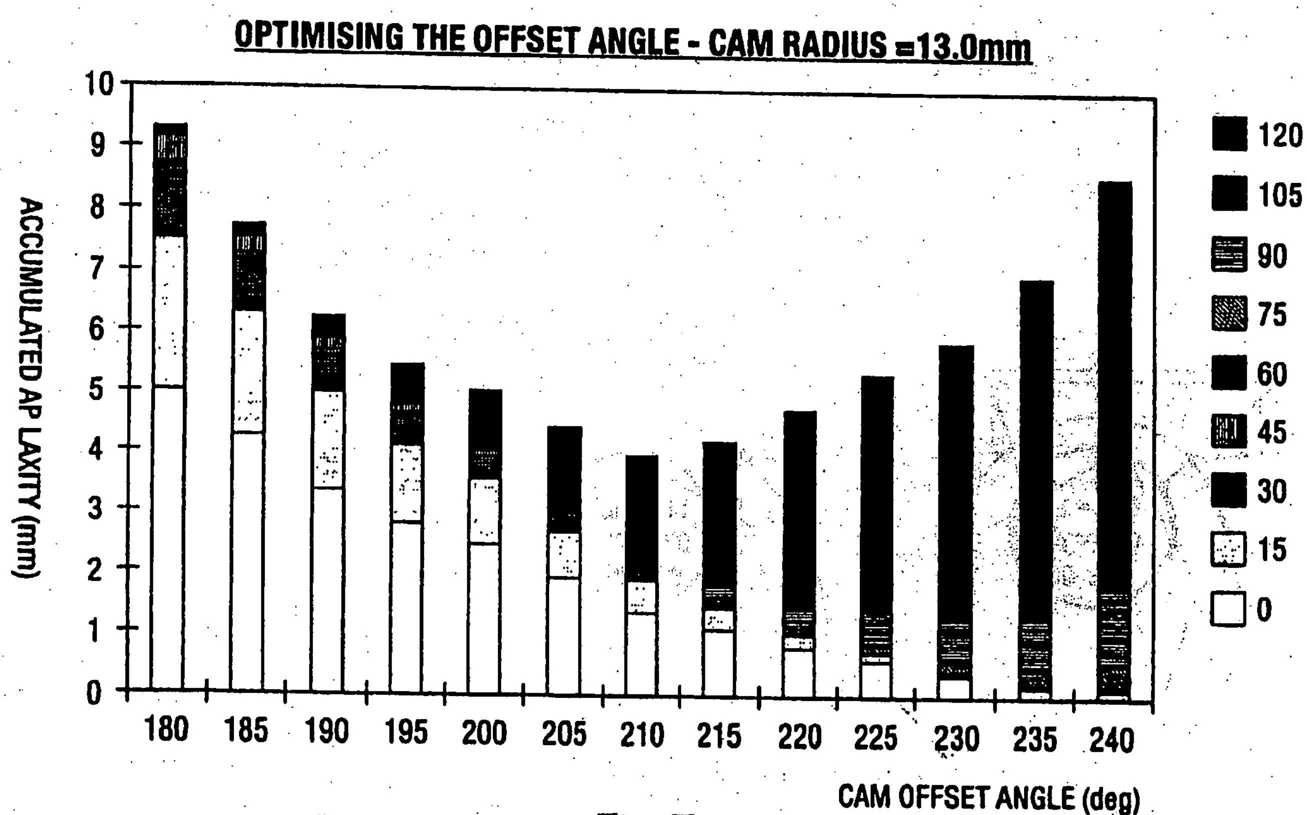
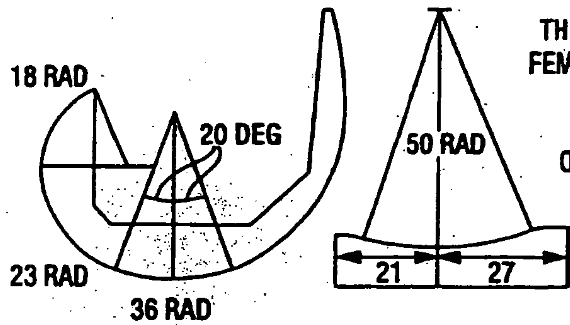

OPTIMISING THE OFFSET ANGLE - CAM RADIUS =13mm
CRITERION 1
CRITERION 2
CRITERION 3
ACCUMULATED AP LAXITY (mm)
34
32
30
28
26
24
22
20
18
16
14
12
10
8
6
4
2
0
CAM OFFSET ANGLE (deg)
180
185
190
195
200
205
210
215
220
225
230
235
240

Fig.5



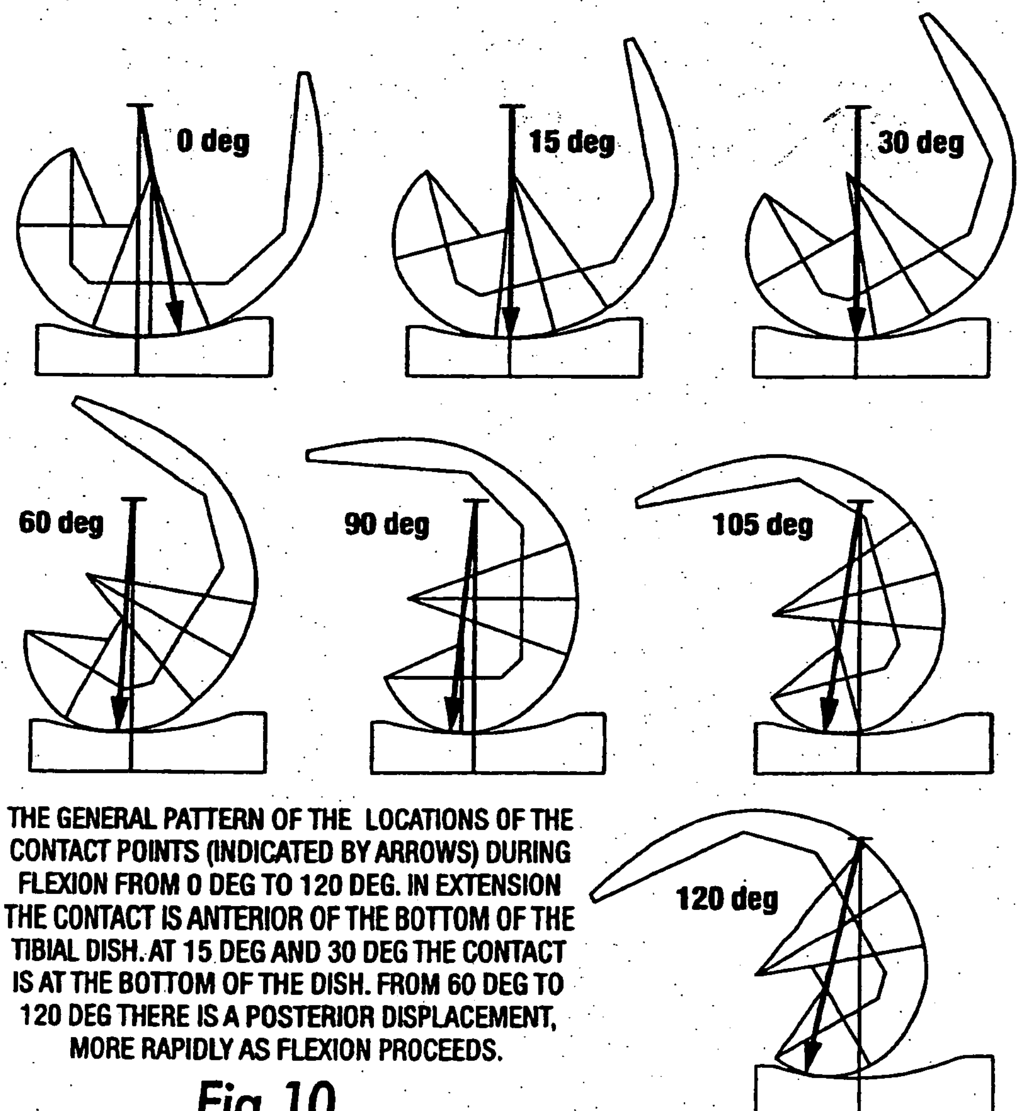
OPTIMISING THE OFFSET ANGLE - CAM RADIUS =13.0mm
ACCUMULATED AP LAXITY (mm)
10
9
8
7
6
5
4
3
2
1
0
180
185
190
195
200
205
210
215
220
225
230
235
240
CAM OFFSET ANGLE (deg)
120
105
90
75
60
45
30
15
0


Fig.7



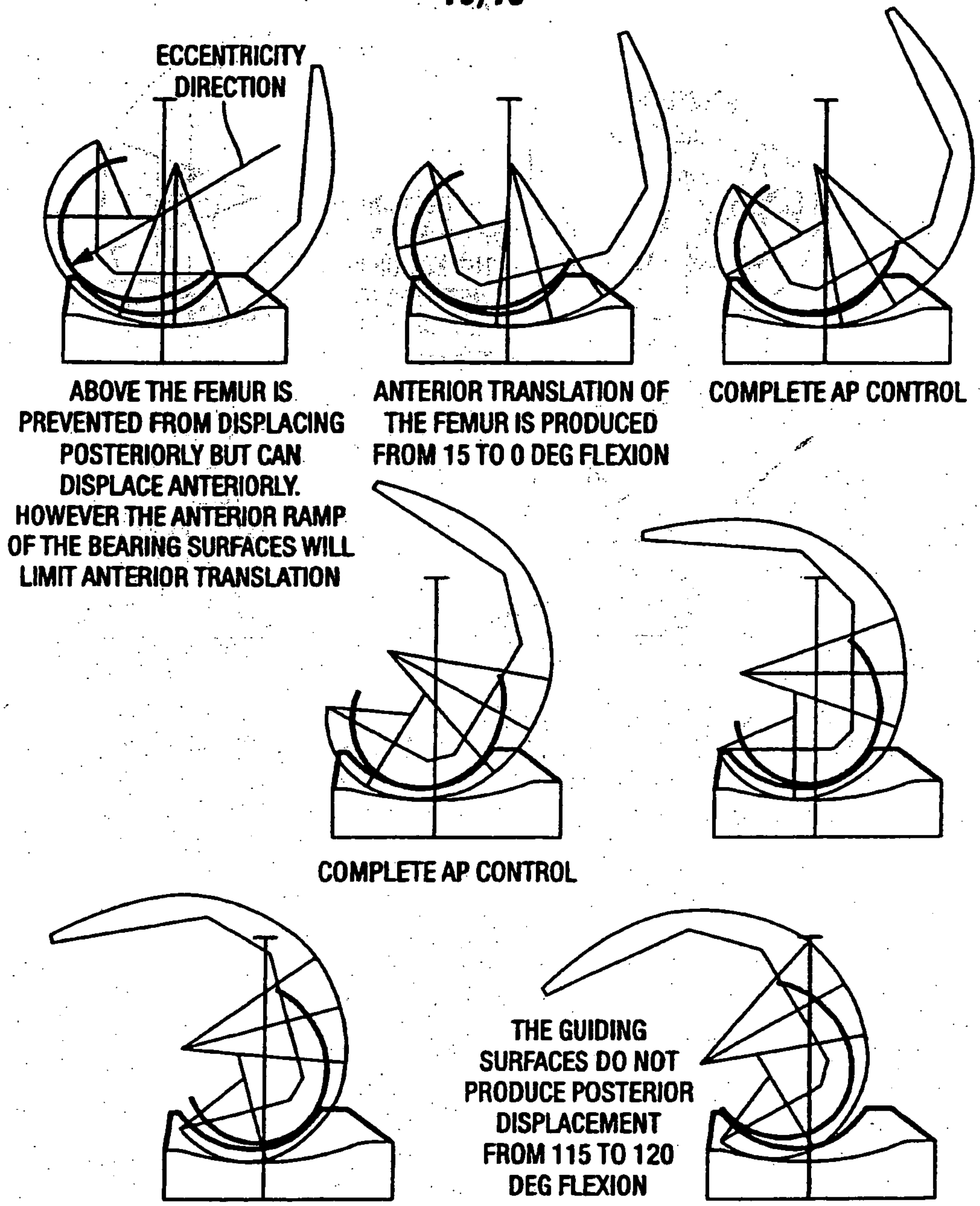

THE SAGITTAL PLANE DIMENSIONS OF THE FEMORAL AND TIBIAL BEARING COMPONENT USED IN THE FOLLOWING FIGURES. THESE ARE TYPICAL DIMENSIONS ONLY, AND OTHER GENERALLY SIMILAR DIMENSIONS ARE APPLICABLE ALSO.

Fig.9



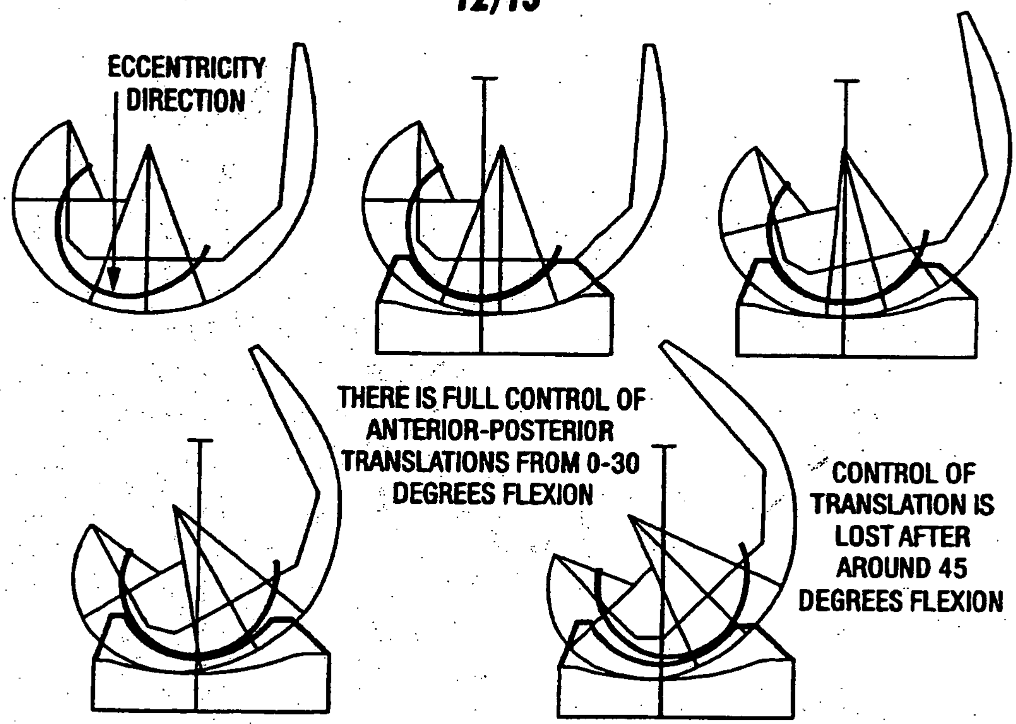

THE GENERAL PATTERN OF THE LOCATIONS OF THE CONTACT POINTS (INDICATED BY ARROWS) DURING FLEXION FROM 0 DEG TO 120 DEG. IN EXTENSION THE CONTACT IS ANTERIOR OF THE BOTTOM OF THE TIBIAL DISH. AT 15 DEG AND 30 DEG THE CONTACT IS AT THE BOTTOM OF THE DISH. FROM 60 DEG TO 120 DEG THERE IS A POSTERIOR DISPLACEMENT, MORE RAPIDLY AS FLEXION PROCEEDS.

Fig.10



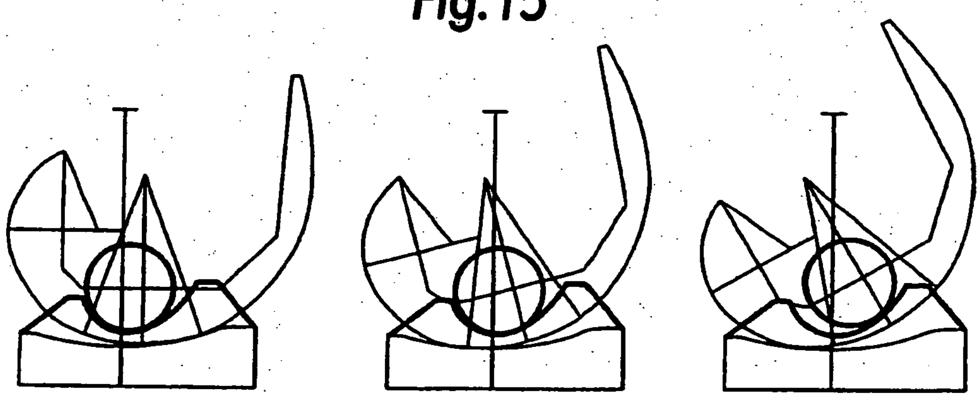

GUIDING SURFACES GENERATED WITH THE ECCENTRICITY ANGLE AT 30 DEGREES BELOW TH HORIZONTAL AND AN ECCENTRICITY OF 5 MM. CORRECTIONS HAVE BEEN MADE AT EACH END OF THE FGS TO IMPROVE FIT WITH THE TGS.

Fig. 12




WHEN THE ECCENTRICITY ANGLE IS 90 DEGREES BELOW THE HORIZONTAL, THERE IS ANTERIOR TRANSLATION AS THE KNEE EXTENDS FROM 15 TO 0 DEGREES. THERE IS FULL CONTROL OF THE TRANSLATIONS UP TO AROUND 30 DEGREES FLEXION. AFTER AROUND 45 DEGREES THERE IS NO CONTROL OF THE TRANSLATIONS.

Fig. 15



WHEN THE RADIUS OF THE FGS IS REDUCED AND THE ECCENTRICITY INCREASED, ANTERIOR-POSTERIOR TRANSLATION IS CONTROLLED IN THE FIRST 30 DEGREES OF FLEXION. ANTERIOR FEMORAL TRANSLATION IS CONTROLLED UP TO AROUND 45 DEGREES AFTER WHICH THERE IS NO CONTROL OF THE TRANSLATIONS.

Fig. 16

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**Knee Prosthesis having Guide Surfaces**
**for Control of Anterior-Posterior Displacement**

This invention relates to a total knee replacement prosthesis (TKR). Total knee replacement involves the surgical removal of the entire natural knee bearing surfaces and their replacement with artificial femoral and tibial components.

The invention is concerned with a type of TKR which includes femoral condylar surfaces which, to some extent, mimic the shape of the natural condyles and an interposed bearing component supported on a tibial platform. Condylar TKRs generally comprise (a) a femoral component having a pair of condylar surfaces, (b) a tibial component having a tibial platform fixed to the resected tibia, and (c) a bearing component usually of low friction plastic material interposed between the condylar surfaces and the tibial platform. The bearing component generally has dished surfaces for receiving the condylar surfaces of the femoral component. The bearing component can be made to be fixed onto the tibial platform or be rotatable and/or slidable in the anterior/posterior direction.

Stability of the artificial knee joint is provided by the dishing of the bearing surfaces and by the ligaments. In all cases, the collateral ligaments are required. In a fixed bearing design with dished bearing surfaces, the stability is sufficient particularly when there is a compressive force acting across the joint. In this situation, the cruciate ligaments are not necessary. For shallow bearing surfaces, which have the advantage of allowing extra freedom of motion, the posterior cruciate ligament is required. The above also applies to a mobile bearing design which only allows rotation. However, when anterior-posterior translation is allowed, the posterior cruciate ligament is required, no matter how dished are the bearing surfaces.

In the natural knee in extension, contact area is central on the tibial bearing surface or even anterior to the centre. As the knee is flexed, the contact area moves progressively posteriorly. This is important in that it provides an increasing

shaped so as to cause the femoral component to be displaced posteriorly during flexion, and displaced anteriorly during extension, and said tibial guide surface being fixed with respect to the tibial platform in an anterior/posterior direction.

Displacement of the femoral component with respect to the tibial component can be effected by 'rigid' body motion or by 'contact' point motion or by a combination of both. In rigid body motion, the femoral component moves bodily with respect to a tibial platform which is fixed to the tibia. Such movement can be effected by permitting a tibial bearing component to be mobile on the tibial platform. On the other hand, the contact point (or centre point of a contact area) between the femoral-tibial bearing surfaces as viewed in a sagittal plane moves during flexion. These relative movements will be discussed in more detail subsequently in this specification in connection with various figures of the drawings. In most cases, there will be a mixture of rigid body and contact point motions.

Preferably, the tibial guide surface has an anterior and posterior upward sweep which engages in recesses in the femoral component to contribute to the stability of the prosthesis at or close to maximum flexion and extension, while anterior-posterior stability is also afforded during the mid-range of flexion due to similar engagements. The tibial guide surface may also include lateral surfaces which engage with corresponding lateral surfaces adjacent to the condylar surfaces of the femoral component.

In one embodiment, the tibial guide surface may be an integral part of the tibial platform, or alternatively be a plastic component fixed relatively to the anterior/posterior direction on the tibial platform. The guide surface may be rotatably mounted on the tibial platform in order to provide internal/external rotation of the knee joint to a desirable degree, e.g. ± 12 to 15 degrees. This kind of arrangement is illustrated in Figures 1A and 1B. Alternatively, the guide surface may be fixed relatively to the tibial platform and the tibial component mounted for rotation within or on a member fixed to the resected tibia. For example, the tibial

17, the contact point motion is more than the rigid body motion. The required anterior/posterior movement of the femoral component on the tibial guide surface is achieved by forming the tibial and/or femoral guide surfaces as cam surfaces so as to cause displacement of the femoral component in the anterior/posterior (A-P) direction with flexion or extension. The aim is to achieve a cam surface allowing only a small amount of A-P laxity or play, so as to control the A-P position throughout the entire range of flexion.

The method of achieving this by a series of iterative incremental angular movements of the component is described below with regard to the accompanying Figures and the invention also includes such method.

In the accompanying drawings:-

Figure 1A is a perspective exploded view of a first embodiment in accordance with the invention;

Figure 1B is a sagittal view of the embodiment shown in Figure 1;

Figures 2, 3 and 4 illustrate the method of determining laxities of the embodiment shown in Figure 1B;

Figure 5 shows graphically the accumulated anterior/posterior laxity at a number of cam offset angles;

Figure 6 shows graphically the accumulated anterior/posterior laxity at a variety of cam radii;

Figure 7 shows graphically accumulated anterior/posterior laxity for different cam offset angles at different degrees of flexion;

Figure 8 illustrates the modification of the guide surfaces to reduce laxity;

Figure 9 shows the radii at different portions of the femoral and tibial bearing components whose movement and interaction is illustrated in Figures 10 to 16;

Figure 10 shows the change in the contact point or areas at different flexions;

Figure 11 illustrates a method of generating the tibial guide surface (TGS) for a given femoral guide surface (FGS);

The FGS is convex, and the TGS is concave. The latter is fixed in an anterior/posterior direction with respect to a metal tibial plate 8, such that by its interaction with the Femoral Guide Surface (FGS), the femoral component can be made to translate relative to the tibia. The starting point for the shape of the FGS is a circular arc of radius RG and centre P which is offset from 0 by a distance EC at an angle of TH from the horizontal. As shown in the detail scrap view in Figure 1B, TH is measured as shown from the horizontal so that an angle greater than 180° represents a centre of curvature P of the FGS which lies below the horizontal plane passing through the centre point O and posteriorly thereof. This is referred to subsequently in this specification as the cam offset angle. As the femur flexes from zero to maximum, it is required that the centre of the femoral component O displaces posteriorly by PT, moving continuously with flexion.

The initial problem is to synthesise the tibial guiding surface, which is depicted as a concave arc of unspecified shape. The heights of the TGS at the anterior and posterior are defined by a stability requirement when the FGS is pressing against the TGS at points C or D. If V is the vertical force across the knee and H is the AP shear force, stability is just achieved when angle GO is given by:

$$\tan(GO) = V/H \qquad (1)$$

The requirement that posterior displacement is positive for all angular increments, is expressed at any flexion angle FLEX as:

$$d(PT)/D(FLEX) > O \qquad (2)$$

For a total range of flexion FM, to satisfy equation (2):

$$(180-FM) > TH > O \qquad (3)$$

This indicates that the line OP lies in the third quadrant. Hence, the largest Y-coordinate of point D is at zero flexion, and of point C is at maximum flexion FM. The Y coordinates of C and D are:

$$YC = RF - [EC.\sin(TH+FM) + RG.\sin(GA)] \qquad (4)$$

$$YC = RF - [EC.\sin(TH) + RG.\sin(GA)] \qquad (5)$$

reduced as follows. It can be visualised that an anterior region of the TGS could be formed as the posterior part of the FGS sweeps over at high flexion angles. It is possible therefore that this anterior region could be filled by an expanded anterior part of the FGS, which would move out of the TGS in early flexion. To examine this possibility, the femur is flexed from zero to FM in the same angular increments as before, and at each angle, each point Q on the FGS for YQ < HT is identified (Fig. 3).

The intersection of P0 with a line segment on the TGS is calculated, point R. RMAX is defined as the upper limit for the radius of the FGS based, for example, on the required dimensions for the pate liar groove. Point V is such that PV = RMAX. The coordinates of Q are changed according to:

If PR<RMAX, XQ = XR, YQ = YR (12)

If PR<RMAX, and PQ<PV,XQ=XV, YQ= YV (13)

By carrying out this procedure it is found that the FGS is expanded in the leading and trailing regions, reducing the laxity. Further iterations for either the FGS or TGS do not result in any further changes.

The final laxity is calculated at each of the angular increments (Fig. 4). Again, each point on the FGS was examined for which YQ < HT. The intersection of a horizontal line through a line segment on the TGS is calculated, and the length OR calculated. QR would be the anterior laxity of the femur if point Q was the first point to contact the TGS. The values of QR for all points on the FGS to the right of L are calculated. The minimum value is the relevant value of the anterior laxity.

The values of anterior and posterior laxity are then used as a criterion for determining the best design of the FGS and TGS. If AL (TH) and PL (TH) are the laxities at any flexion angle TH, the following criteria are considered:

$$\text{Minimise: } FI = \sum_{O}^{FM} (AL\,(TH) + PL\,(TH)) \qquad \text{criterion (1)}$$

This minimises the overall AP laxity throughout motion, but gives equal weight to a small number of large displacements or a large number of small displacements.

**Results**

Of the two parameters, the FGS cam offset angle TH, and the FGS cam radius RG, the former was the most influential. Figure 5 shows the A-P laxity values for the three criteria. For criterion 1, the accumulated laxities for the 5 flexion positions 0, 30, 60, 90,120) were the least at only 4 mm for a TH of 210°. The laxity increased to 10 mm at the extremes of TH. Criterion 2 gave the same minimum point at 210°, with exaggerated differences at the extremes due to the square function. Criterion 3 again gave TH = 210° as the minimum, with a maximum laxity of only 1.3 mm as against 5 mm at the extremes of TH.

For a TH of 210°, the variation of the laxity values for the three criteria, as a function of cam radius RG, are shown in Figure 6. There was little difference between 13 mm and 18 mm, but below 13 mm there was an increase in laxity. Figure 7 shows at which angles of flexion the largest laxities occurred, for a range of TH values. For TH less than the optimum of 210°, there were greater laxities at the smaller flexion angles; at TH values greater than 210° the opposite was the case. At a TH of 210°, the largest laxities occurred equally at the extremes of flexion, O° and 120°.

It will thus be seen that for good control over posterior roll back, the centre of curvature of the TGS should lie posteriorly and downwardly from the major centre of curvature of the condylar surfaces, O. Typically, the cam offset angle may preferably be between about 190 and 230°.

The Femoral and Tibial Guide Surfaces (FGS, TGS) are shown for a cam with radius 13 mm offset at 210° in Figure 8. Relative to the original circular shape of the FGS, it is seen that additional material has been added at O° flexion and at 120° flexion, effectively increasing the peripheral radii of the cam. The small (1.3 mm) laxities can also be seen at O° and 120° with negligible laxities in the mid-range of flexion.

a contact point just posterior of the centre of the tibial bearing surface provides adequate lever arm for the quadriceps. Beyond 60 degrees, an increasingly posterior contact point further increases the quadriceps lever arm. Finally, beyond 105 degrees, a more rapid posterior translation of the contact point is an advantage for maximising the range of flexion. The sequence of contact points is represented generally, and the precise locations can vary by say 2-3 millimetres from those shown.

Given a typical sagittal geometry for the femoral and tibial bearing surfaces, and the sequence of contact points, the rigid body motion of the femur can be determined geometrically. The method for synthesising the TGS for a given FGS has been described in mathematical terms above. The method can also be illustrated graphically (Fig. 11). The femur is positioned on the tibial bearing surface in the sequence of positions shown in Figure 10. The TGS needs to accommodate the multiple positions of the FGS. The TGS is then defined by the locus of the convex side of the multiple FGS positions. The anterior and posterior heights of the TGS are defined based on the required stability, or subluxation height. As described previously, the FGS can be subsequently modified by adding material at the anterior and posterior, which reduces the laxity at the extremes of motion. The resulting FGS and TGS still allow some laxity at the extremes, but overall, there is limitation of both anterior and posterior displacements, more especially in the mid-range of flexion.

Using the method for generating the femoral and tibial guide surfaces described above, the configuration is shown which produces the least overall laxity, regardless of which criterion is used (Fig. 12). The FGS is convex and the TGS concave. With the knee in extension, there is a small gap allowing the contact point to slide anteriorly. In the mid-range of flexion there is complete control of anterior-posterior displacement up to 105 degrees. With this basic configuration of the FGS and TGS, a useful posterior translation of the contact points occur with flexion. However, at 120 degrees flexion, the Guide Surfaces do not produce the

base plate 8. The femoral condyles 2 and 3 are bridged by a femoral guide surface 6, having a generally convex form when viewed sagittally as shown in Figure 1B. Close conformity of the condylar surfaces with the dished areas of the bearing component (the plastic component) when viewed in transverse cross-section is also desirable.

A tibial guide surface 7 has anterior and posterior up-sweeps 9 and 10, which both provide the anterior and posterior guidance and also assist in stability by engaging within recesses such as 11 within the femoral component. In addition, the lateral surfaces of the tibial guide surface component engages with corresponding lateral surfaces internally of the condyles 2 and 3 to provide lateral stability.

Figure 17 shows another embodiment in which the tibial guide surface 20 is formed as an integral part of the bearing component 21. Similarly, the femoral guide surface 22 may still be formed as an intercondylar surface but may be blended into the shape of the condyles 2 and 3. The latter may consist of conventionally shaped sagittal and frontal femoral profiles in contact with tibial bearing surfaces designed to be swept out by the femoral surfaces as they move through the maximum flexion range. In this embodiment, the tibial bearing surfaces need to allow for the anterior/posterior displacement, and the internal/external rotation. This could be achieved by making the tibial surfaces flat, thereby providing unrestricted rotational movement. Preferably, however, there should be some restraint and this can be achieved by making the tibial platform shallow at the centre, but upwardly curved at the anterior and posterior so as to limit the rotation to say $\pm 12°$. Alternatively, a sagittal radius can be provided in partial conformity with the femoral bearing surfaces to allow progressive restraint from the neutral position. In all these cases, the tibial guide surface will need to be modified to allow for the internal/external rotation. This can be achieved by generating a locus of the femoral guide surface as before, but including internal/external rotation at each flexion angle.

**CLAIMS:-**

1. A condylar total knee replacement prosthesis which comprises:

(a) a femoral component adapted to be fixed to the femur and having a pair of condylar surfaces;

(b) a tibial component adapted to be fixed to the tibia and having a tibial platform; and

(c) a bearing component which is interposed between the condylar surfaces and the tibial platform and has lateral and medial dished bearing surfaces adapted to support the femoral condylar surfaces,

said femoral component having an intercondylar guide surface which is adapted to engage a corresponding tibial guide surface on the tibial platform or on the bearing component, the intercondylar surface being rounded and having a centre of curvature when viewed sagitally, which is offset from a major centre of curvature of the femoral condylar surfaces, said offset being approximately one half of the distance of intended posterior displacement of the femur on the tibia.

2. A prosthesis as claimed in claim 1 wherein the intercondylar guide surface has a radius of at least 10 mm.

3. A prosthesis as claimed in claim 1 or 2 wherein the posterior displacement is a small value at low degrees of flexion and increases to a maximum at high degrees of flexion.

4. A prosthesis as claimed in any one of the preceding claims wherein the condylar surfaces show close conformity with the dished portions of the tibial bearing surfaces when viewed in the frontal plane.

5. A prosthesis as claimed in claim 4 wherein the tibial bearing surfaces are mobile on the tibial platform.

6. A prosthesis as claimed in any one of the preceding claims wherein the tibial guide surface has an anterior and posterior upward sweep, which engages in recesses in the femoral component to contribute to the stability of the prosthesis at or close to maximum flexion and extension.

14. A prosthesis as claimed in claim 12 or 13 wherein the bearing component is shaped to provide upright surfaces extending in the A-P direction and inwardly of the dished lateral and medial areas, said upright surfaces engaging with corresponding surfaces on the femoral component, whereby the prosthesis is stabilized in a lateral-medial direction.

15. A prosthesis as claimed in any one of claims 12 to 14 wherein the bearing component is mounted on the tibial platform so as to allow for about ± 12 degrees of internal/external rotation.

16. A prosthesis as claimed in any one of claims 12 to 15 wherein the bearing component is mobile in an A-P direction on said tibial platform.

17. A modification of the prosthesis claimed in any one of claims 12 to 16 wherein the femoral and tibial bearing surfaces are shaped to perform the function of femoral and tibial guide surfaces, an intercondylar guide surface being optional.

18. A prosthesis as claimed in any one of claims 12 to 17 wherein the femoral condylar surfaces are notched anteriorly to permit hyperextension while retaining conformity with the tibial bearing surfaces in a sagittal plane.

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